

VII. Regulatory Impact Analysis

Section 804(2) of title 5, United States Code (as added by section 251 of Public Law 104-121), specifies that a "major rule" is any rule that the Office of Management and Budget finds is likely to result in--

! An annual effect on the economy of \$100 million or more;

! A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

! Significant adverse effects on competition, employment, investment productivity, innovation, or on the ability of United States based enterprises to compete with foreign based enterprises in domestic and export markets.

We estimate, based on a simulation model, that the redistributational effects on HHAs participating in the Medicare program associated with this final rule would range from a positive \$428 million for freestanding not-for-profit agencies to a negative \$363 million for freestanding for-profit agencies in FY 2001. Therefore, this rule, is a major rule as defined in Title 5, United States Code, section 804(2).

We have examined the impacts of this final rule as required by Executive Order 12866, the Unfunded Mandates

Reform Act of 1995, (Public Law 104-4), and the Regulatory Flexibility Act (RFA) (Public Law 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually). Section 1895(b)(3)(A)(i) of the Act requires that the total amounts payable under the HHA PPS be equal to the total amount that would have been paid if this system had not been in effect. Section 302 of the BBRA amends section 1895(b)(3)(A)(ii) of the Act and delays the application of a 15 percent reduction in HHA PPS payment amounts until 1 year after its implementation. Section 306 of the BBRA amends section 1895(b)(3)(B)(ii) of the Act to require the standard prospective payment amounts to be increased by a factor equal to the home health market basket minus 1.1 percentage points for each of FYs 2002 and 2003. In addition, for subsequent fiscal years, the law requires the rates to be increased by the applicable home health market basket index change. Thus, subject to these adjustments, the statutory construction of

this final rule is budget neutral. However, we are aware that there would be a number of organizational accommodations that must be made by HHAs in order to make the transition from the cost-based/interim payment system environment to a prospective payment environment that would result in costs to these entities. On that basis, we are preparing this RIA.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in any given year. We believe that the costs associated with this final rule that apply to these governmental sectors would fall below this threshold. Therefore, the law does not apply and we have not prepared an assessment of anticipated costs and benefits of this final rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and governmental agencies. Most HHAs are considered small entities, either by nonprofit status or by having revenues of \$5 million or less annually.

Table 10 illustrates the distribution of HHAs by provider type participating in Medicare as of March 16, 2000.

Table 10--Number of HHAs by Provider Type

HHA Provider Type	Number of HHAs
Visiting Nurse Association	451
Combination of Government & Voluntary	35
Official Health Agency	910
Rehabilitation Facility Based	0
Hospital Based	2278
Skilled Nursing Facility Based	161
Other	3801
Total	7636

Source: HCFA - On Line Survey Certification and
Reporting System Standard Report 10 - March 16,
2000.

The following RIA/RFA analysis, together with the rest of this preamble, explains the rationale for and purposes of this final rule.

A. Background

This final rule establishes requirements for the new prospective payment system for home health agencies as required by section 4603 of the Balanced Budget Act of 1997, as amended by section 5101 of OCESAA and sections 302, 305,

and 306 of BBRA. The requirements include the implementation of a prospective payment system for home health agencies and a number of other related changes. The prospective payment system described in this rule would replace the retrospective reasonable cost-based system currently used by Medicare for the payment of home health services under Part A and Part B. This final rule sets forth a prospective payment system for all costs of home health services under section 1895 of the Act.

B. Revisions to the Proposed Rule

Below are listed a number of the significant changes to the proposed rule that are reflected in the final rule.

Section 409.100

Section 305 of the BBRA excludes DME covered as a home health service from the consolidated billing requirements. Specifically, the law requires, "in the case of home health services (including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who (at the time the item or service is furnished) is under the plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others

under arrangement with them made by the agency, or when any other contracting or consulting arrangement, or otherwise)."

However, under HHA PPS there is a separate payment for DME items and services currently provided as a home health service and paid under the DME fee schedule. As discussed earlier, under the HHA PPS, DME covered as a home health service as part of the Medicare home health benefit will continue to be paid under the DME fee schedule. Further, in accordance with the statute, as amended by section 305 of BBRA, DME is also excluded from the consolidated billing requirements. A separate payment amount in addition to the prospective payment amount for home health services will be made for DME currently covered as a home health service under the PPS.

HHAs will no longer be able to "unbundle" home health services (other than DME) to an outside supplier that can then submit a separate bill directly to the Part B carrier or DMERC. Instead, the HHA itself will have to furnish the home health services (except DME) either directly or under an arrangement with an outside supplier in which the HHA itself, rather than the supplier, bills Medicare. The outside supplier must look to the HHA rather than to Medicare Part B for payment, except in the case of DME. Beneficiaries

receiving DME prior to establishment of a home health plan of care can continue the relationship with that same DME supplier. The consolidated billing requirement eliminates the potential for duplicative billings for the same services to the RHHI by the HHA and to the Part B carrier by an outside supplier. All covered home health services listed in section 1861(m) (including medical supplies described in section 1861(m)(5), but excluding DME to the extent provided in such section) of the Act under a plan of care must be billed by the HHA.

Section 484.205

! We revised paragraph (a)(1) and (b) to clarify that the osteoporosis drug covered under the home health benefit is the only home health service listed in section 1861(m) of the Act that continues to be paid on a reasonable cost basis under PPS.

! We added paragraphs (b)(1) and (b)(2) that provides for the requirements governing the final split percentage payment approach. New paragraph (b)(1) governs the split percentage payment approach for initial episodes. The initial percentage payment for initial episodes is paid at 60 percent of the case-mix and wage adjusted 60 day episode rate. The residual final payment for initial episodes is paid at 40

percent of the case-mix and wage adjusted 60 day episode rate. New paragraph (b)(2) governs the split percentage payment approach for subsequent episodes. The initial percentage payment for subsequent episodes is paid at 50 percent of the case-mix and wage adjusted 60 day episode rate. The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage adjusted 60 day episode rate.

Section 484.215

We revised paragraph (d)(4) to reflect the amounts that are added to the nonstandardized episode amount for the OASIS adjustment for the one time implementation costs associated with assessment scheduling form changes and amounts for Part B therapies that could have been unbundled to Part B prior to PPS implementation.

Section 484.225

We revised paragraph (c) to reflect that for each of FYs 2002 and 2003 the rates are updated by the applicable home health market basket minus 1.1 percentage points.

Section 484.230

We revised the language in this section to reflect the higher per-visit amounts that will be used to calculate the LUPA payments.

Section 484.235

We revised paragraph (b) to reflect the use of billable visit dates as the defining points for the PEP adjustment.

Section 484.237

We revised paragraphs (b)(1) and (b)(2) governing the SCIC adjustment to reflect the use of billable visit dates to define the span of days used to calculate the proportional payments both before and after a patient experiences a significant change in condition.

Section 484.240

We revised paragraph (d) to reflect the higher per-visit amounts that will be used to calculate the imputed costs for each episode for outlier payment determination.

C. Effects of this Final Rule

Section 1895(b)(3)(A)(i) of the Act requires the computation of a standard prospective payment amount to be initially based on the most recent audited cost-report data available to the Secretary. In accordance with this section of the Act, the primary data source in developing the cost basis for the 60-day episode payments was the audited cost-report sample of HHAs whose cost reporting periods ended in fiscal year 1997 (that is, ending on or after October 1, 1996 through September 30, 1997). We also adopted the most current

complete utilization data available from 1998.

Table 11 below illustrates the proportion of HHAs that are likely to be affected. This table reflects how agencies would be paid under PPS versus how they would be paid under IPS. The limits under IPS were determined by updating the per-visit limits in effect for FY 2000 by the market basket minus 1.1 percent and updating each agency's per-beneficiary cap for FY 2000 by this same percentage. For each agency in the audited cost report data set, we updated their costs from FY 1997 to FY 2001 by our best estimate of HHA cost increases during this period. We then compared each agency's FY 2001 costs to the IPS limits to determine their IPS payment in FY 2001. To determine each agency's payment under PPS, we translated the cost report data into 60-day episodes and used the average case-mix for urban/rural and provider type as a proxy. We extrapolated the audited cost report data to reflect the total Medicare HHA distribution. We obtained average case-mix values based on the type of provider and whether the HHA was urban or rural from the Abt data set. We then multiplied the agency's expected number of episodes in FY 2001 by the wage-adjusted and case-mix-adjusted episode payment to obtain the agency's expected PPS payment. The PPS payment was then compared to the IPS payment.

**Table 11--Impact of the Home Health Prospective Payment
Amounts on Home Health Agencies by Type and Location for the
563 Audited Cost Report Sample Agencies**

Type of Agency	Percentage Change from IPS to PPS
All Agencies	0.0
By Urban/Rural and Provider Type:	
Rural:	
Freestanding: For-Profit	-7.50
Governmental	29.98
Non-Profit	13.28
Provider Based	5.31
Urban:	
Freestanding: For-Profit	-14.25
Governmental	20.58
Non-Profit	18.89
Provider Based	-2.50
By Provider Type:	
Freestanding: For-Profit	-12.77
Governmental	26.50
Non-Profit	17.88
Provider Based	-1.03
By Urban/Rural:	
Rural Agencies	5.94
Urban Agencies	-0.08
By Region:	
Midwest States	14.77
Northeast States	15.37
Southern States	-16.75

Type of Agency	Percentage Change from IPS to PPS
Western States	17.84

Table 11 represents the projected effects of the HHA PPS and is based on the 563 providers in the audited cost-report sample weighted to the national total of HHAs. This sample has been adjusted by the most recent market basket factors to reflect the expected cost increases occurring between the cost-reporting periods for the data contained in the database and September 30, 2001.

This impact table compares the effect on categories of HHAs in moving from the IPS payment methodology to the PPS payment methodology. These cost limits have already had the effect of reducing many extremes in the cost of the system; therefore, as a result of IPS, a majority of HHA providers are currently held at the median national cost per-beneficiary or below. It should be noted that HHAs will have had 2 or more years experience under this system before PPS implementation. The effect of IPS payment restraint combined with the improvements in this final rule have significantly reduced the degree of variation between providers and regions as well as the overall impact of the rule. Because we believe it was

important that the impact tables provide the most accurate representation possible, it was necessary for us to use the data set drawn upon from the audited cost report file. This file of course is nationally representative and these data become decreasingly valid when divided into smaller geographic areas. Thus, the lowest level of analysis we could reasonably provide using this data is the four census regions. Any finer level of analysis would introduce a level of statistical error that we believe would be unacceptable.

Column one of this table divides HHAs by a number of characteristics including provider type, region, and urban versus rural location. For purposes of this impact table four regions have been defined: Northeast, South, Midwest, and West. The Northeast Region consists of Connecticut, Massachusetts, Maine, New Hampshire, New Jersey, New York, Pennsylvania, Puerto Rico, Rhode Island, Vermont, and the Virgin Islands. The South Region consists of Alabama, Arkansas, the District of Columbia, Delaware, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia. The Midwest Region consists of Iowa,

Illinois, Indiana, Kansas, Michigan, Minnesota, Missouri, North Dakota, Nebraska, Ohio, South Dakota, and Wisconsin. The West Region consists of Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, New Mexico, Nevada, Oregon, Utah, Washington, and Wyoming.

Column two shows the percentage change in Medicare payments a particular category of HHAs would experience in moving from the IPS payment methodology to the final PPS payment methodology. Because the statute requires aggregate payments under the HHA PPS and HHA IPS payment methodology to be budget neutral, the effect on agencies in the aggregate is zero.

Rural freestanding for-profit HHAs experience an 7.50 percent decrease in moving from the IPS payment methodology to the PPS payment methodology. Rural freestanding governmental HHAs experience an 29.98 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Rural freestanding nonprofit HHAs experience an 13.28 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Rural provider-based HHAs, in the aggregate, experience an 5.31 percent increase in moving from the IPS payment methodology to the PPS

payment methodology. Rural agencies, in the aggregate, experience an 5.94 percent increase in moving from the IPS payment methodology to the PPS payment methodology.

Urban freestanding for-profit HHAs experience an 14.25 percent decrease in moving from the IPS payment methodology to the PPS payment methodology. Urban freestanding governmental HHAs experience an 20.58 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Urban freestanding nonprofit HHAs experience an 18.89 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Urban provider-based HHAs, in the aggregate, experience an 2.50 percent decrease in moving from the IPS payment methodology to the PPS payment methodology. Urban agencies, in the aggregate, experience an 0.08 percent decrease in moving from the IPS payment methodology to the PPS payment methodology.

The current IPS cost limits have been criticized as providing better financial treatment of urban providers relative to rural providers. The HHA PPS system, which is based on patient characteristics, tends to level the playing field; thus, rural providers, in general, fare relatively better than urban providers. The largest

impact on urban providers is in the urban freestanding for-profit category where it can be argued that historical costs have been disproportionately high compared to other providers for reasons unrelated to the relative needs of the patients they serve.

Freestanding for-profit HHAs, in the aggregate, experience an 12.77 percent decrease in moving from the IPS payment methodology to the PPS payment methodology. Freestanding governmental HHAs, in the aggregate, experience an 26.50 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Freestanding nonprofit HHAs, in the aggregate, experience an 17.88 percent increase in moving from the IPS payment methodology to the PPS payment methodology. Provider-based HHAs, in the aggregate, experience an 1.03 percent decrease in moving from the IPS payment methodology to the PPS payment methodology.

It should be noted that governmental providers fare relatively better under the HHA PPS system than other types of providers. In part, this is because the HHA PPS system is driven primarily by the needs of patients rather than utilization incentives. Thus, governmental providers are less affected by the IPS payment

methodology because their costs have been historically lower and visit utilization per episode is much lower. On average, governmental agencies have reported lower average costs per visit as well as fewer visits per episode. It should be noted that this category of HHAs accounts for only 3.8 percent of total home health expenditures and, therefore, the large increase attributed to them has little impact in the aggregate system costs.

Provider-based agencies historically tended to have, as a group, higher per-visit costs. As could be anticipated, the payment differential reflected in this impact table for provider-based agencies is in a negative direction, but relatively modest, probably due to the cost discipline already in place due to IPS.

HHAs in the Midwest region experience an 14.77 percent increase in moving from the IPS payment methodology to the PPS payment methodology. HHAs in the Northeast region experience an 15.37 percent increase in moving from the IPS payment methodology to the PPS payment methodology. HHAs in the South region experience an 16.75 percent decrease in moving from the IPS payment methodology to the PPS payment methodology. HHAs in the

West region experience an 17.84 percent increase in moving from the IPS payment methodology to the PPS payment methodology.

We would have preferred to provide an impact table with more regions; however, the limitations of our data prevented us from obtaining provider data at a lower level than the four major regions. However, this regional breakdown does reflect what one might expect in moving from our current IPS cost limitations payment methodology to a national PPS payment methodology. Medicare payments have historically varied by region without regard to the relative needs/conditions of patients; therefore, that region that had the highest unexplained costs for home health services is the most impacted area (South region). In contrast, the Midwest, Northeast, and West regions fare relatively well by comparison. It must be noted that in a payment methodology system that is legislatively required to achieve budget neutrality, any effort to increase payments to those regions more affected by a national payment system necessarily results in a reduction of payments to those regions that have historically restrained costs under home health.

It should be noted that to the degree that agencies respond to the incentives of the prospective payment system and apply resources commensurate with the measured characteristics of their patients, the impacts predicted in this model will further be reduced.

D. Rural Hospital Impact Statement

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

We have not prepared a rural impact statement since we have determined, and the Secretary certifies, that this rule would not have a significant economic impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism. We have determined that this final rule would not have substantial direct effects on the rights, roles, and responsibilities of States.